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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,548	11/19/2003	Edward M. Sellers	62805.000040	5852
21967	7590	10/19/2006		
HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER
DATE MAILED: 10/19/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/715,548	Applicant(s) SELLERS ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,17,21,31-33 and 38-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 6,17,21,31-33 and 38-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 6, 17, 21, 31-33 and 38-54 are pending in this application.

Election/Restrictions

Claim 49 recites the limitation "the method of claim 10" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because claim 10 has been cancelled. Further, it is unclear what method is being claimed because upon consideration of claim 10 for clarification of the method, claim 10 is drawn to a composition. Accordingly, for the purpose of an election, claim 49 is being interpreted as a composition claim and is placed in group III, drawn to a pharmaceutical composition. However, if the group III invention is elected, clarification is required.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 6, drawn to a method of screening for a substance that regulates nicotine metabolism to cotinine, classified in class 435, subclass 7.92.
- II. Claim 17, drawn to a method for enhancing inhibition of nicotine metabolism by a CYP2A6 inhibitor, classified in class 514, subclass 922.
- III. Claims 21 and 49, drawn to a pharmaceutical composition comprising an inhibitor of CYP2A6 and an inhibitor of CYP2B6, classified in class 514, subclass various.
- IV. Claims 31-33, drawn to a method for determining the CYP2A6 activity in an individual containing two mutant alleles, one mutant allele, or no

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mutant allele at a gene locus CYP2A6 classified in class 435, subclass 332.

- V. Claim 38, drawn to a method for treating a condition requiring regulation of nicotine metabolism to cotinine, classified in class 514, subclass 922.
- VI. Claims 39-48, 52 and 53 drawn to a method of regulating the metabolism of nicotine to cotinine, classified in class 514, subclass 343.
- VII. Claims 50-51 and 54, drawn to a method for treating dependent tobacco use, classified in class 514, subclass 813.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation, in that the method of screening for a substance that regulates nicotine metabolism to cotinine in Group I is not required for the Group II invention, a method for enhancing inhibition of nicotine metabolism by a CYP2A6 inhibitor.

Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product, a pharmaceutical composition comprising an inhibitor of CYP2A6 and an inhibitor of

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CYP2B6, can be used in a materially different process of using that product, such as pilocarpine, can be used for glaucoma.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have modes of operation, in that the method for determining the CYP2A6 activity in an individual containing two mutant alleles, one mutant allele, or no mutant allele at a gene locus CYP2A6 of the Group IV invention has a different mode of operation than the Group III invention, drawn to a composition comprising an inhibitor of CYP2A6 and an inhibitor of CYP2B6.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation in that the method for treating a condition requiring regulation of nicotine metabolism to cotinine of the Group V invention has a different mode of operation from the Group IV invention, drawn to the method for determining the CYP2A6 activity in an individual containing two mutant alleles, one mutant allele, or no mutant allele at a gene locus CYP2A6.

Inventions V and VI are directed to related conditions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as

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claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a different function, in that the group V invention is drawn to a method for treating a condition requiring the regulation of nicotine metabolism to cotinine. The Group VI invention is drawn to a method of regulating the metabolism of nicotine to cotinine. There is not requirement that a condition be present in order for the regulation of metabolism of nicotine to cotinine to occur. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation in that the Group VI invention is drawn to a method of regulating the metabolism of nicotine to cotinine and the Group VII invention is drawn to a method for treating dependent tobacco use. There is no issue of dependency on tobacco in the group VI invention.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

If the group VI invention is elected:

Claim 42 is generic to the following disclosed patentably distinct species: opioid related disorders, proliferative diseases, cognitive disorders, neurological disorders, mental disorders, other drug dependencies, malignant disease, psychosis, schizophrenia, Parkinson's disease, anxiety, depression, alcoholism, dependent tobacco use, non-dependent tobacco use and opiate dependence. The species are independent or distinct because they are not related and would require a separate search for each of the conditions listed.

If either group VI or group VII is elected:

Claims 46 and 51 are generic to the following disclosed patentably distinct species: coumarin, furanocoumarin, methoxsalen, imperatorin, psoralen, alpha naphthoflavone, isopimpinellin, beta naphthoflavone, bergapten, sphondin, coumatetralyl (racumin), (+)-cis-3,5-dimethyl-2-(3-pyridyl)-thiazolidim-4-one, naringenin, related flavones, diethyldithiocarbamate, N-nitrosodialkylamine, nitropyrene, menadione, imidazole antimycotics, miconazole, clotrimazole, pilocarpine, hexamethylphosphoramide, 4-methylnitrosamine-3-pyridyl-1-butanol, aflatoxin B.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with

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this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the Examiner knows from past experience that a telephone election will not be made, see MPEP Sect. 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

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record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

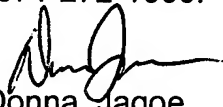
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Donna Jagoe
Patent Examiner
Art Unit 1614

October 5, 2006

 10/14/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER